

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

UNITED STATES OF AMERICA)	
)	Criminal No. 22-cr-10150
v.)	
)	
SOLERA SPECIALTY PHARMACY, LLC)	
)	
Defendant)	

DEFERRED PROSECUTION AGREEMENT

The United States Attorney’s Office, by its attorney, Rachael S. Rollins, United States Attorney for the District of Massachusetts (the “Office”), and Defendant, Solera Specialty Pharmacy, LLC (“Solera”), a Florida limited liability company with its principal place of business in Pompano Beach, Florida hereby enter into the following Deferred Prosecution Agreement (“Agreement”):

1. **Charges:** Solera consents to the filing in the United States District Court for the District of Massachusetts of an Information charging it with one count of health care fraud, in violation of Title 18, United States Code, Section 1347. Specifically, the Information charges Solera with having knowingly and willfully executed a scheme and artifice to defraud Medicare, a health care benefit program as defined in Title 18, United States Code, Section 24(b), and to obtain, by means of materially false and fraudulent pretenses, representations, and promises, money and property owned by, and under the custody and control of, Medicare, in connection with the delivery of and payment for health care benefits, items, and services, in violation of Title 18, United States Code, Section 1347.

Solera knowingly waives its right to indictment on these charges and agrees to venue of the case in the District of Massachusetts. Solera further knowingly waives any applicable statute of limitations and any legal or procedural defects in the Information.

2. **Acceptance of Responsibility:** Solera accepts and acknowledges responsibility for its conduct and that of its employees as set forth in the Statement of Facts attached hereto as Exhibit A and incorporated herein by reference (the “Statement of Facts”). If the Office, pursuant to Paragraph 6, initiates a prosecution that is deferred by this Agreement against Solera, Solera agrees that it will neither contest the admissibility of the Statement of Facts, nor contradict in any such proceeding the facts contained within the Statement of Facts. Solera waives and forgoes any right under the United States Constitution, Rule 410 of the Federal Rules of Evidence, Rule 11(f) of the Federal Rules of Criminal Procedure, or any other rule, that any statements made by or on behalf of Solera prior or subsequent to this Agreement, or any leads derived therefrom, shall be inadmissible, suppressed, or otherwise excluded from evidence at any judicial proceeding arising from this Agreement.

3. **Parallel Civil Settlement:** Simultaneous with the execution of this agreement, Solera and the United States are entering into a Civil Settlement Agreement to settle certain civil claims in connection with the same conduct that is the subject of the Information (the “Civil Settlement Agreement”). Solera shall make payments over time as set forth in the Civil Settlement Agreement, for a total payment amount of \$1,310,000 plus interest.

4. **Deferral of Prosecution:** In consideration of Solera’s remedial actions to date and its willingness to: (a) acknowledge and accept responsibility for its actions;

(b) settle civil claims the United States has against Solera and pay the civil settlement amount within the period set forth in the Civil Settlement Agreement; (c) continue its cooperation with the United States; (d) demonstrate its future good conduct and full compliance with federal law; and (e) comply with the obligations set forth herein:

a. *Deferred Prosecution:* The Office agrees that it will recommend to the Court that prosecution of Solera on the Information be deferred for the duration of this Agreement. If the Court declines to defer prosecution for any reason, this DPA shall be null and void, and the parties will revert to their pre-DPA positions.

b. *The Term:* This Agreement is effective for a period beginning on the date on which the Information is filed, and ending 36 months from that date (the “Term”). Solera expressly waives all rights to a speedy trial pursuant to the Sixth Amendment of the United States Constitution for the Term of this Agreement. Moreover, Solera agrees: (1) to join the government in seeking to exclude, pursuant to Title 18, United States Code, Section 3161(h)(2), the Term of this Agreement from the time within which trial of the offense charged in the Information must commence, for the purpose of allowing Solera to demonstrate its good conduct; and (2) to waive any rights to a speedy trial under Federal Rule of Criminal Procedure 48(b).

c. *Extension of the Term:* Solera agrees that, in the event the Office determines in its sole discretion that Solera has knowingly and materially violated any provision of this Agreement, an extension of the Term of the Agreement may be imposed by the Office, in its sole discretion, for up to an additional 12-month period, without prejudice to the right of the Office to proceed as provided in Paragraph 6 below. Any extension of the Agreement extends all terms of the Agreement.

d. *Completion of the Term:* The Office shall, if Solera is in full compliance with all of its obligations under this Agreement, within 30 days of the expiration of the Term of this Agreement set forth above in Paragraphs 4(b) and (c), or earlier at the discretion of the Office, seek dismissal with prejudice of the Information filed against Solera pursuant to Paragraph 1, and this Agreement shall expire and be of no further force or effect. The Office further agrees not to file charges in the future against Solera relating to the Statement of Facts, the Information, or facts currently known to the Office regarding Solera's prior authorization and co-payment practices. Specifically excluded from this non-prosecution provision is any action the United States may take, civil or criminal, relating to federal tax matters.

5. **Commitment to Compliance and Remedial Actions:** As part of this Agreement, Solera agrees that it shall comply with the following terms:

a. *Prior Authorizations:* Solera agrees that Solera and its employees, agents, and representatives shall not provide false or otherwise misleading information, including but not limited to clinical information, in prior authorization or non-formulary exception requests to insurers or pharmacy benefit managers, and shall not obscure Solera's involvement in the process in any way. Solera shall implement and maintain a standard operating procedure concerning its prior authorization practices designed to ensure Solera's compliance with federal health care program laws and plan rules, as set forth in Exhibit B.

b. *Co-Payment Obligations:* Solera agrees that Solera and its employees, agents, and representatives shall not waive or otherwise intentionally fail to collect any co-payment obligation under a federal health care benefit program except as

provided by law or statutory exception. Solera shall maintain documentation supporting all determinations of financial hardship in connection with any such co-payment waivers.

c. *Legal Compliance:* Solera agrees to fully comply with federal laws with respect to purchasing, selling, billing, and dispensing pharmaceutical products, including without limitation Title 42, United States Code, Sections 1320a-7a and 1320a-7b.

d. *Compliance Program:* Solera agrees it will continue to implement compliance procedures and training designed to ensure that all of Solera's directors, officers, employees, agents, and representatives fully comply with federal laws and regulations related to purchasing, selling, billing, and dispensing pharmaceutical products.

e. *Integrity Agreement:* Solera agrees to abide by any and all requirements of any Integrity Agreement and Conditional Exclusion Release by and between Solera and the Office of Inspector General of the United States Department of Health and Human Services regarding remedial measures or other required actions related to the conduct outlined in the Statement of Facts.

f. *Civil Settlement:* Solera agrees to abide by any and all requirements in the Civil Settlement Agreement with the United States.

g. *Notification:* Solera agrees to notify the Office of any government criminal, civil, administrative, or regulatory investigation of or action against Solera or its current directors, officers, employees, agents, or representatives related to Solera's compliance with federal laws and regulations related to purchasing, selling, billing, and dispensing pharmaceutical products.

6. **Breach of the Agreement:** If the Office determines that Solera has committed a willful and material breach of any provision of this Agreement, the Office shall provide written notice to Solera's counsel of the alleged breach and provide Solera with a two-week period from the date of receipt of said notice, or longer at the discretion of the Office, in which to make a presentation to the Office to demonstrate that no breach has occurred or, to the extent applicable, that the breach is not willful or material, or has been cured. The Office agrees to consider such explanation in determining whether to institute a prosecution of Solera. The parties expressly understand and agree that if Solera fails to make the above-noted presentation within such time, it shall be presumed that Solera is in willful and material breach of this Agreement. The parties further understand and agree that the Office's exercise of discretion under this paragraph is not subject to review in any court or tribunal outside the Department of Justice and the United States Attorney's Office for the District of Massachusetts. In the event of a breach of this Agreement that results in a prosecution, such prosecution may be premised upon any information provided by or on behalf of Solera to the Office or any investigative agencies, whether prior to or subsequent to this Agreement, and/or any leads derived from such information, including the attached Statement of Facts, unless otherwise agreed to by the Office and Solera in writing at the time the information was provided to the government.

7. **Waiver of Rights:** Solera hereby further expressly agrees that within six months of a willful and material breach of this Agreement by Solera, any violations of federal law that were not time-barred by the applicable statute of limitations as of the date of this Agreement that: (a) relate to the Statement of Facts; or (b) were hereinafter discovered by the Office, may in the sole discretion of the Office be charged against Solera,

notwithstanding the provisions or expiration of any applicable statute of limitations. In the event of a willful and material breach, Solera expressly: waives any challenges to the venue or jurisdiction of the United States District Court for the District of Massachusetts; waives any right to be charged by an Indictment returned by a grand jury; and agrees to be prosecuted on the Information filed in this matter or a superseding Information arising from the facts presented in the Statement of Facts.

8. **Requirement to Obey the Law:** If the Office determines during the term of this Agreement that Solera has committed any federal crime after the date of the signing of this Agreement, Solera shall, in the sole discretion of the Office, thereafter be subject to prosecution for any federal crimes of which the Office has knowledge, including but not limited to the conduct described in the Statement of Facts. The discovery by the Office of any purely historical criminal conduct that did not take place during the term of the Agreement will not constitute a breach of this provision.

9. **Parties Bound by the Agreement:** This Agreement and all provisions set forth herein bind Solera, which agrees to ensure that any wholly owned subsidiaries, affiliates, and successors comply with the requirements and obligations set forth in this Agreement. It is further understood that this Agreement and all provisions set forth herein are binding on the Office. It is further understood that this Agreement does not bind any federal agencies, or any state or local authorities, although the Office will bring the cooperation of Solera and its compliance with its other obligations under this Agreement to the attention of federal, state, or local prosecuting offices or regulatory agencies, if requested by Solera or its attorneys. Nothing in this Agreement restricts in any way the ability of the Office, any other federal department or agency, or any state or local

government from proceeding criminally, civilly, or administratively, against any current or former directors, officers, employees, agents, or representatives of Solera or against any other entities or individuals. The parties to this Agreement intend that the Agreement does not confer or provide any benefits, privileges, immunities, or rights to any other individual or entity other than the parties hereto.

10. **Severability:** Any provision of this Agreement that is prohibited or unenforceable shall be ineffective to the extent of such prohibition or unenforceability without invalidating the remaining provisions hereof.

11. **Public Statements:** Solera agrees that it shall not cause to be made, through its attorneys, agents, officers, employees, consultants, or authorized agents (including, contractors, subcontractors, or representatives), including any person or entity controlled by any of them, any public statement contradicting the acceptance of responsibility by Solera set forth above or the facts described in the Statement of Facts. Any such public statement by Solera, its attorneys, agents, officers, employees, consultants, contractors, subcontractors, or representatives, including any person or entity controlled by any of them, shall, subject to the cure rights of Solera set forth below, constitute a willful and material breach of this Agreement as governed by Paragraph 6 of this Agreement, and Solera would thereafter be subject to prosecution pursuant to the terms of this Agreement. The decision of whether any public statement by any such person contradicting the acceptance of responsibility by Solera set forth above or the facts described in the Statement of Facts will be imputed to Solera, for the purpose of determining whether Solera has breached this Agreement, shall be in the sole discretion of the Office. If the Office determines that Solera has made a public statement contradicting its acceptance of responsibility or any fact

contained in the Statement of Facts, the Office shall so notify Solera. Upon the Office's notification to Solera of a public statement by any such person that in whole or in part contradicts the acceptance of responsibility by Solera set forth above or the facts described in the Statement of Facts, Solera may avoid breach of this Agreement by publicly repudiating such statement within 5 business days after notification by the Office. Solera shall be permitted to raise defenses and to assert affirmative claims in other proceedings relating to the matters set forth in the Statement of Facts provided that such defenses and claims do not contradict, in whole or in part, a statement contained in the Statement of Facts. This paragraph does not apply to any statement made by any present or former officer, employee, or agent of Solera in the course of any criminal, regulatory, or civil case initiated against such individual, unless such individual is speaking on behalf of Solera. Subject to this paragraph, Solera retains the ability to provide information or take legal positions in litigation or other regulatory proceedings in which the United States is not a party.

12. Solera agrees that if it or any of its agents or affiliates issues a press release or holds any press conference in connection with this Agreement, Solera shall first consult the Office to determine: (a) whether the text of the release or proposed statements at the press conference are true and accurate with respect to matters between the Office and Solera; and (b) whether the Office has any objection to the release.

13. **Conduct Covered by Agreement:** It is further understood that this Agreement does not relate to or cover any conduct by Solera other than for any act within the scope of the Statement of Facts, the Information, or facts currently known to the Office regarding Solera's prior authorization and co-payment practices.

14. **Public Filing:** Solera and the Office agree that this Agreement (and its attachments) and an Order deferring prosecution shall be publicly filed in the United States District Court for the District of Massachusetts.

15. **Complete Agreement and Notice:** This Agreement sets forth all the terms of the Agreement between Solera and the Office. There are no promises, agreements, or conditions that have been entered into other than those expressly set forth in this Agreement and in the Civil Settlement Agreement, and none shall be entered into and/or be binding upon Solera or the Office unless signed by the Office, Solera's attorneys, and a duly authorized representative of Solera. This Agreement supersedes any prior promises, agreements, or conditions between Solera and the Office. Solera agrees that it has the full legal right, power, and authority to enter into and perform all of its obligations under this Agreement and it agrees to abide by all terms and obligations of this Agreement as described herein.

16. Any notice, certification, resolution, or report to the Office under this Agreement shall be given by personal delivery, overnight delivery by a recognized delivery service, or registered or certified mail, to:

Chief, Health Care Fraud Unit
U.S. Attorney's Office for the District of Massachusetts
John Joseph Moakley Federal Courthouse
One Courthouse Way, Suite 9200
Boston, MA 02210

17. Any notice to Solera under this Agreement shall be given by personal delivery, overnight delivery by a recognized delivery service, or registered or certified mail, addressed to:

Solera Specialty Pharmacy, LLC
2100 Park Central Blvd N
Suite 300
Pompano Beach, Florida 33064

Anthony Mahajan, Esq.
Frier Levitt, LLC
84 Bloomfield Avenue
Pine Brook, NJ 07058

18. Notice shall be effective upon actual receipt by the Office or Solera.

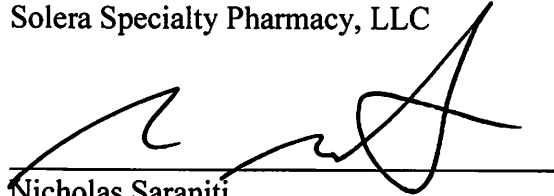
19. This Agreement, to become effective, must be signed by all of the parties listed below. No promises, agreements, terms, or conditions other than those set forth in this Agreement will be effective unless memorialized in writing and signed by all parties or confirmed on the record before the Court.

**ACKNOWLEDGMENT ON BEHALF OF
SOLERA SPECIALTY PHARMACY, LLC**

I, Nicholas Saraniti, Chief Executive Officer, the duly authorized representative of Solera Specialty Pharmacy, LLC, hereby expressly acknowledge the following: (1) that I have read this entire Agreement as well as the other documents filed herewith in conjunction with this Agreement, including the Information and Statement of Facts; (2) that I have had an opportunity to discuss this Agreement fully and freely with Solera's counsel, Frier Levitt, LLC; (3) that Solera fully and completely understands each and every one of the terms of this Agreement; (4) that Solera is fully satisfied with the advice and representation provided to it by its counsel, Frier Levitt, LLC; (5) that I am authorized, on behalf of Solera, to enter into this Agreement; and (6) that Solera has signed this Agreement knowingly and voluntarily.

6/29/2022
DATE

Solera Specialty Pharmacy, LLC



Nicholas Saraniti
Chief Executive Officer
Solera Specialty Pharmacy, LLC

**ACKNOWLEDGMENT BY COUNSEL
OF SOLERA SPECIALTY PHARMACY, LLC**

I, Anthony J. Mahajan, the attorney representing Solera Specialty Pharmacy, LLC, hereby expressly acknowledge the following: (1) that I have reviewed and discussed this Agreement with my client; (2) that I have explained fully each one of the terms of the Agreement to my client; (3) that I have answered fully each and every question put to me by my client regarding the Agreement; and (4) that I believe my client fully and completely understands all of the Agreement's terms.

7/6/22
DATE



Anthony J. Mahajan
Frier Levitt, LLC

**ON BEHALF OF THE UNITED STATES ATTORNEY'S OFFICE
FOR THE DISTRICT OF MASSACHUSETTS**

RACHAEL S. ROLLINS
UNITED STATES ATTORNEY

July 8, 2022

DATE



DAVID J. DERUSHA
ABRAHAM R. GEORGE
AMANDA P.M. STRACHAN
Assistant U.S. Attorneys

EXHIBIT A

**STATEMENT OF FACTS FOR SOLERA SPECIALTY PHARMACY
DEFERRED PROSECUTION AGREEMENT**

Defendant Solera Specialty Pharmacy, LLC (“Solera”) hereby agrees and stipulates that at all times relevant to the Information pending against it in the United States District Court for the District of Massachusetts in *United States v. Solera Specialty Pharmacy, LLC*, Criminal No. 22-cr-10150, the following was true and accurate:

1. Solera was a Florida limited liability company with its principal place of business in Pompano Beach, Florida.

2. Solera was a specialty pharmacy that dispensed high-cost treatments that are less commonly available at traditional retail pharmacies, such as drugs that treat chronic illnesses like HIV, Hepatitis C, and rheumatoid arthritis.

3. Evzio was a prescription naloxone hydrochloride injection used to treat a person known or suspected to have had an opioid overdose. Evzio delivers a single dose of the drug naloxone via a voice-guided, hand-held auto-injector.

4. Evzio was significantly more expensive than other prescription naloxone products with which it competed. Whereas Evzio’s list price was \$4,100 for a pack of two auto-injectors, the competing Narcan nasal spray was available for roughly \$150 per two-pack, and generic injectable naloxone was available for less than \$12 per dose.

5. Pharmacies that dispensed Evzio could earn significant profit margins on Evzio—typically about \$400 per Evzio pack.

6. Solera dispensed Evzio from in or about January 2017 to in or about May 2018.

7. Solera knew that many Medicare Part D plans would not authorize payment for Evzio without a prior authorization request. In the prescription drug context, insurers may direct providers to seek prior authorization, a process which requires the provider to submit additional

clinical information justifying the prescription before insurers will agree to pay. Prior authorization forms commonly ask providers whether a patient to whom a drug has been prescribed is intolerant to (or has already tried but failed on) a less costly alternative therapy. Ordinarily, a physician or the physician's office completes a prior authorization request and sends it to the insurer with the physician's signature.

8. Solera employed several individuals who held the title "Patient Navigator." Among other duties, Patient Navigators worked on completing and submitting prior authorization requests for Evzio. As part of the prior authorization process, Medicare Part D plans required the submission of clinical information regarding the Medicare beneficiary prior to approving coverage. Part D plans often required this clinical information to be provided directly by representatives of the prescribing physician's office.

9. Solera completed Evzio prior authorization forms in place of the prescribing physicians, including instances in which Solera staff signed the prior authorization forms without the physician's authorization. Solera then submitted the forms to insurers—including to Medicare Part D plans—as if Solera were the physician. On dozens of Evzio prior authorization request forms, Solera staff listed Solera's fax number in a field that requested the prescribing physician's fax number. In addition, Solera listed the name of a Solera employee in a field on the prior authorization forms that called for the prescribing physician's office contact. Solera did so to ensure that insurers would contact Solera—and not the listed prescribing physician—when communicating about the prior authorization request.

10. In addition to purporting to be the physician's office, Solera submitted Evzio prior authorization requests to insurers that contained false clinical information to secure approval of the prior authorization and payment for the more expensive drug. For example, Solera staff

filled out and submitted dozens of Evzio prior authorization request forms that falsely asserted that patients had previously tried and failed both Narcan and naloxone. Furthermore, Solera staff falsely stated on Evzio prior authorization request forms that patients had previously been hospitalized or resided in areas with long wait times for emergency services. At times, Solera staff re-used prior authorization request forms with such false justifications by whiting out the patient's name and unique identifiers but leaving the purportedly patient-specific clinical details unchanged.

11. Insurers, including Medicare Part D plans, approved dozens of false Evzio prior authorization requests that Solera submitted. Solera understood that had the insurers known that the forms contained false information, they would not have authorized and paid for the prescriptions.

12. In addition, Solera knew that patients prescribed Evzio frequently had co-payment obligations. Insurance plans, including Medicare Part D plans, obligated Solera, as the dispensing pharmacy, to collect co-payments. For Evzio, co-payments could range from a few dollars to hundreds of dollars, depending on the terms of the patient's insurance coverage.

13. For commercially insured patients, Evzio's manufacturer offered a co-payment assistance program that waived the patient's out-of-pocket expense for the drug. Solera knew that such co-payment assistance programs could not be applied to subsidize or waive out-of-pocket expenses for beneficiaries of government health care programs like Medicare, and that applying such subsidies would violate the federal Anti-Kickback Statute.

14. Solera knew that government health care programs like Medicare do not authorize payment for a prescription if the claim for payment resulted from a violation of the Anti-Kickback Statute. Nevertheless, Solera waived Medicare beneficiary co-payment obligations for

Evzio on numerous occasions without analyzing whether the beneficiary had a genuine financial hardship.

15. Solera understood that had the Medicare Part D plans known that Solera had waived Evzio co-payment obligations absent individualized considerations of financial hardship, they would not have authorized payment for those prescriptions.

16. Solera failed to adequately oversee and train staff responsible for the prior authorization and co-payment process.

EXHIBIT B

**Solera Specialty Pharmacy
Standard Operating Procedure**

Title: Processing of Prior Authorization Requests	Responsible Department:
Date Issued: _____, 2022	Approved By:

DEFINITION:

Prior authorization is a procedure by which health care providers are required to obtain advance approval from a health plan for a specific procedure, service, or medication to qualify for payment coverage.¹

POLICY:

It is the policy of Solera Specialty Pharmacy (“Pharmacy”) to ensure that all efforts made in a patient’s prior authorization process are truthful, accurate, legally compliant, ethical and in accordance with payor contractual requirements. To the extent the Pharmacy participates in the prior authorization process for any prescription claim, it does so for the sole purpose of ensuring patients timely receive medically appropriate medications that have been prescribed by their treating clinicians, and based on the reasonable belief that the medication prescribed is in the best interests of the patient to receive. Pharmacy’s efforts in the prior authorization process are to enhance communication and cooperation between different healthcare providers, and to streamline the process by which patients receive their medications, and Pharmacy does not intend for its efforts in the prior authorization process to serve as an inducement to referring prescribers or to patients.

Pharmacy may not, at any point, make any assurances to a prescriber or the patient regarding the approval, or likelihood of approval, of any prior authorization that it will prepare or submit. Moreover, the Pharmacy shall not prioritize any patient’s prior authorization over another based upon the volume or value of referrals submitted by that patient’s prescriber. All steps described in the Procedure below must be performed in compliance with Federal and State laws, including the Health Insurance Portability and Accountability Act.

Any suspected non-compliance with this Policy or applicable Federal or State law shall be reported to the Pharmacy’s Compliance officer.

Throughout this policy, the term “CoverMyMeds” shall include the CoverMyMeds portal as well as any similar online portals that may be used to process, complete, and/or submit prior authorization requests.

PROCEDURE:

The following procedures govern the process of prior authorization requests at the Pharmacy:

1. The Pharmacy may receive certain prescription medication orders that require prior authorization before dispensing. The Pharmacy provides prior authorization assistance services at no cost. Where

¹ *Prior Authorization: The Current Landscape*, American Medical Association; *See also Prior Authorization Practice Resources*, American Medical Association, <https://www.ama-assn.org/practice-management/sustainability/prior-authorization-practice-resources>.

not otherwise prohibited or limited by law or pharmacy benefit manager (“PBM”) contract, the Pharmacy makes the services available to *all* patients and prescribers, without regard to the volume or value of referrals a prescriber submits to the Pharmacy.

2. Upon processing a claim for prescription coverage, the Pharmacy shall check the patient’s profile or claims submission messaging to determine if the electronic claim(s) needs prior authorization. The Pharmacy shall check the electronic claims’ log for rejection information and verify active coverage for the date submitted.
3. Upon determining that a prior authorization is required, the Pharmacy shall determine whether the prior authorization request will require information from or involvement by the prescriber, or whether the prior authorization requirement is directed solely at the Pharmacy. In the event that the prior authorization request will require information from or involvement by the prescriber, the Pharmacy shall contact the prescriber and request permission to assist with the prior authorization request process on behalf of the prescriber for the identified patient.
4. The Pharmacy shall check the patient’s profile to obtain the current insurance processing information to determine where and how the prior authorization will be submitted.

a. *If the insurer/PBM requires the prescriber to submit the Prior Authorization:*

- i. *Hard Copy/Fax Prior Authorization Forms:* The Pharmacy will collect and input all necessary information to accurately and truthfully complete the insurer’s or PBM’s required form(s) and will send the draft form(s) to the prescriber for submission, along with any information and instructions regarding the process by which the prescriber should complete the prior authorization request per any claims rejection messaging. The prescriber **must** be the one to submit the prior authorization request to the insurer or PBM, and the Pharmacy may not submit the prior authorization request to the insurer or PBM. The Pharmacy will use reasonable efforts in following up with prescribers’ offices to ensure that prior authorization requests are timely submitted, and will communicate updates on the status of the process to patients.
- ii. *ePrior Authorization:* If the insurer/PBM utilizes CoverMyMeds for prior authorizations, the Pharmacy will make reasonable efforts to obtain all necessary information from the patient or prescriber to accurately and truthfully complete the prior authorization request to the fullest extent possible, as appropriate, using the Pharmacy’s own CoverMyMeds profile. Once the Pharmacy has completed prior authorization request to the greatest extent possible with truthful and accurate information, the Pharmacy will click the “Send to Prescriber” button to cause the request to be digitally transmitted to the prescriber for review, verification and submission to the insurer/PBM. The Pharmacy will use reasonable efforts in following up with prescribers’ offices to ensure that prior authorization requests are timely submitted, and will communicate updates on the status of the process to patients. The pharmacy will not utilize a prescriber’s CoverMyMeds profile to complete or submit prior authorization requests.

- b. If the insurer/PBM permits the Pharmacy to submit Prior Authorization:
- i. Upon receipt of a prescription drug order which requires prior authorization, Pharmacy will collect and input all necessary information to accurately and truthfully complete the insurer's or PBM's required form(s). If additional patient information is required, a Patient Navigator will make reasonable efforts to obtain such information from the prescriber (or if the prescriber is unreachable, from the patient), as appropriate, until the prior authorization request is finalized for submission. The Pharmacy shall obtain all necessary medical notes and lab values from the prescriber's office, along with all tried-and-failed medications (if any), that would facilitate a prior authorization request to be submitted to the patient's insurer or PBM. The Pharmacy shall document in the patient's profile the source from which it obtained the relevant information, including the identity of the individual within the prescriber's office from whom the information was obtained, as well as the date/time that each piece of information is obtained.
 - ii. ePrior Authorization: If prior authorization is being submitted by way of CoverMyMeds, the Pharmacy employee must take the following steps:
 1. Select "PA Web Request" from the claim rejection detail screen to launch CoverMyMeds with auto-generated prior authorization forms
 2. If PA Web Request does not select the correct form, enter processing information and select the correct prior authorization form associated with the patient's insurance plan
 - a. Verify all information transferred from pharmacy software system to CoverMyMeds.
 - b. Add/correct any missing/inaccurate information.
 - c. If anything is wrong in this process, inform IT **immediately**.
 - d. Gather all information necessary from the prescriber and/or patient to populate the prior authorization form.
 - e. Populate the prior authorization form with truthful and accurate information obtained from the prescriber.
 - f. Upload the necessary documents that have been updated from the prescriber and/or patient.
 - g. The Pharmacy must review the prior authorization form. Upon the Pharmacy's review and confirmation, the Pharmacy must document the review with a note in the patient's chart.
 - h. If all information is truthful, accurate and complete, the Pharmacy may click "Send to Plan" through the Pharmacy's CoverMyMeds profile (where permitted) to transmit the prior authorization request to the insurer or PBM. Under no circumstances will the Pharmacy sign the form on a line calling for the signature or approval of the prescriber.
 - i. The Pharmacy shall save a copy of the prior authorization request in the patient's profile. The Pharmacy shall also transmit a copy of the prior authorization request to the prescriber.

iii. Hard Copy/Fax Prior Authorization Forms: If prior authorization is being submitted by way of fax or mail, the Pharmacy employee must take the following steps:

1. When the prior authorization form requires the prescriber's signature and date on the bottom, the pharmacist and/or pharmacy **must not** sign the form; the prescriber **must** sign the form. The Pharmacy may populate the prior authorization fax form with true and accurate clinical information that the Pharmacy received from the prescriber's office.
 - a. The Pharmacy must review the populated prior authorization fax form to ensure accuracy before sending the form back to the prescriber's office. The Pharmacy must document the review with a note in the patient's chart.
 - b. The prior authorization fax form must then be sent back to the prescriber's office for the prescriber's review and signature. The prescriber may then submit the form to the patient's insurance plan, or the prescriber may send it back to the pharmacy after the prescriber's signature for Pharmacy's submittal. If the prescriber sends the form back to the Pharmacy after signature, the Pharmacy shall submit it to the patient's insurance company.
2. If the prior authorization form permits the pharmacy to sign the form or does not require a signature, the Pharmacy shall take the following steps:
 - a. Gather all information necessary from the prescriber and/or patient to populate the prior authorization form.
 - b. Populate the prior authorization form with truthful and accurate information obtained from the prescriber.
 - c. Append the necessary documents that have been updated from the prescriber and/or patient.
 - d. The Pharmacy must review the prior authorization form. Upon the Pharmacy's review and confirmation, the Pharmacy must document the review with a note in the patient's chart.
 - e. If all information is truthful, accurate and complete, the Pharmacy may click "Send to Plan" through the Pharmacy's CoverMyMeds profile (where permitted/enabled) to transmit the prior authorization request to the insurer or PBM. Under no circumstances will the Pharmacy sign the form on a line calling for the signature or approval of the prescriber.
 - f. The Pharmacy shall save a copy of the prior authorization request in the patient's profile. The Pharmacy shall also transmit a copy of the prior authorization request to the prescriber.
5. In all interactions with the insurer or PBM regarding the prior authorization process, the Pharmacy employee will clearly identify himself as a representative of the Pharmacy calling on behalf of one of its patients. The employee will **not** identify himself as a representative of the prescriber, a member of the prescriber's staff or otherwise suggest that they are employed by the prescriber (i.e., Pharmacy employee may not say they are calling "on behalf of the prescriber"; however, Pharmacy employee may say that they "have been authorized by the patient's prescriber to assist in the prior authorization process," provided the patient's prescriber has granted that authorization). The Pharmacy may call the patient's insurer or PBM to determine the status of the prior authorization as

long as the staff member clearly indicates he or she is calling from the Pharmacy. Under no circumstances may the Pharmacy provide untruthful or misleading information or statements during all such interactions with the insurer or PBM.

6. Unless otherwise instructed by the insurer/PBM, the Pharmacy is not authorized to fill any prescription requiring a prior authorization until a prior authorization is granted, nor may the Pharmacy enter overrides for emergency fills.
7. Pharmacy will follow all Prior Authorization Standards from its URAC 3.1/ACHC Accreditations. To the extent the terms of such Prior Authorization Standards conflict with the provisions of this Standard Operating Procedure, the terms of this Standard Operating Procedure shall apply.
8. The Pharmacy may assist in creating a “draft” letter of medical necessity, if required by a particular insurance plan or PBM, to be based on facts and circumstances specific to the applicable patient (i.e., actual diagnoses, prior treatments, lab values), and referencing acceptable and reputable medical and pharmacologic literature. Once the draft letter of medical necessity is created and reviewed by a pharmacist, the pharmacist shall send the draft letter of medical necessity to the prescriber’s office (in editable Microsoft Word format) for prescriber review (and revisions, if necessary), signature, and submittal to the patient’s insurer or PBM. Where permitted by law and applicable insurer or PBM requirements, the prescriber may also send the form back to the Pharmacy for the Pharmacy’s submittal to the patient’s insurance company or PBM.
9. The Pharmacy and its employees will refrain from undertaking any of the following actions:
 - a. Signing prior authorization request forms on behalf of the prescriber;
 - b. Falsely representing that they are employed by or affiliated with the prescriber in communications with third parties;
 - c. Utilizing false or misleading information when completing prior authorization requests;
 - d. Completing prior authorization requests without confirming and documenting the accuracy of the submitted information with the prescriber and/or patient;
 - e. Masking the Caller ID information or outgoing facsimile number for the Pharmacy’s telephone number to obscure the source of calls or facsimiles to insurance companies or PBMs;
 - f. Providing misleading or deceptive statements in communications with the prior authorization departments of insurance companies and PBMs;
 - g. Creating additional or “dummy” CoverMyMeds accounts for purposes of submitting prior authorizations; and/or
 - h. Utilizing the login credentials for prescribers’ CoverMyMeds accounts or otherwise submitting prior authorizations using prescribers’ CoverMyMeds accounts.

Related Policies:

Policy Updated: